

PATENT
Attorney Docket No. 225011
DHHS Ref. No. E-133-1990/0-US-03

COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION AND POWER OF ATTORNEY EXECUTED BY ASSIGNEE FOR REISSUE APPLICATION

☒ Declaration Submitted with Initial Filing OR
☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

As a representative for the assignee, I hereby declare that:

I believe the named inventors to be original, first, and joint inventors of the subject matter which is claimed and for which a reissue of U.S. Patent 6,114,397 (hereinafter "the original patent") is sought on the invention entitled:

GOSSYPOL FOR THE TREATMENT OF CANCER

the specification of which:

☐ is attached hereto.
☒ was filed on March 22, 2004, as Application No. 10/806,088 and was amended on *(if applicable)*.
☐ was filed by Express Mail No. *as Application No. not known yet*, and was amended on *(if applicable)*.
☐ was filed on as PCT International Application No. PCT/ and was amended on *(if any)*.

I have reviewed and understand the contents of the specification identified above, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Foreign priority benefits are claimed under 35 USC 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application(s) designating at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application(s) for patent, utility model, design registration, inventor's or plant breeder's rights certificate(s), or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter and having a filing date before that of the application(s) from which the benefit of priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Claimed YES	NO	Certified Copy Attached? YES	NO
			☐	☐	☐	☐
			☐	☐	☐	☐
			☐	☐	☐	☐
			☐	☐	☐	☐

The original patent is believed to be wholly or partly inoperative or invalid by reason of the patentees claiming, without deceptive intent, more than the patentees had the right to claim in the patent. Specifically, the independent claims 1 and 8 of the original patent encompass the use of racemic gossypol to treat cancer in a human. However, it has recently been discovered that the post-operative administration of racemic gossypol to patients, following surgical resection of bladder tumors, was disclosed in a prior art reference unknown to patentees during the prosecution of the original patent. The prior art reference is an article in a Russian medical journal, namely Yerukhimov et al., "Treatment of Bladder Tumors with Gossypol and Ionol in Combination with Surgical Intervention," *Voprosy Onkologii* XII (1966). The prior art reference and the aforementioned error were discovered after issuance of the original patent.

All errors being corrected in the reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of the patentees.

The below-listed individuals are inventors in this reissue application with their respective residence and country of citizenship following.

Mary R. Flack, Kensington, MD	Country of Citizenship: US
Richard Knazek, Bethesda, MD	Country of Citizenship: US
Marcus Reidenberg, Scarsdale, NY	Country of Citizenship: US

The assignee hereby appoints the National Institutes of Health, Office of Technology Transfer, 6011 Executive Blvd., Ste. 325, Rockville, Maryland 20852-3804, Telephone (301) 496-7056, as Principal Attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith: Customer Number 05318.

05318

Please recognize Leydig, Voit, & Mayer, Ltd. as Associate Attorneys in this case: Customer Number 23460.

23460

Please direct correspondence concerning this application to Leydig, Voit & Mayer, Ltd.: Customer Number 23460.

23460

I have reviewed the assignment records and certify that, to the best of my knowledge and belief, title of the original patent is vested in the United States of America as represented by the Secretary of the Department of Health and Human Services, as evidenced by the assignment recorded on August 28, 1990, beginning at Reel 5416, Frame 0858, of the Assignment Division Records in the U.S. Patent and Trademark Office.

I am authorized to sign this document on behalf of the assignee, inasmuch as the National Institutes of Health, Office of Technology Transfer, has been duly delegated responsibility for patent matters under the authority of DHHS Secretary Louis W. Sullivan's May 21, 1991, memorandum published in the Friday, June 7, 1991, Federal Register Notices at Vol. 56, Pages 26418-26419 (copy attached).

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: July 13, 2004

By: Jasbir S. Kindra
Jasbir S. Kindra
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